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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howard 6,129,685 in view of Tillander 3,674,014.

Howard discloses a system comprising: a sheath 1103, having a sheath body; a lumen extending through the sheath from the proximal to the distal end; a catheter 1105 having a catheter body and a distal end that terminates in a distal tip; an energy source 1107 coupled to the distal tip; a magnetically active element 1104 forming a portion of the distal end of the sheath body sufficient to align the distal tip of the sheath generally with respect to the direction of an applied magnetic field (Fig. 27B); and a magnet outside the body that applies a magnetic field of sufficient strength to align the magnetically active element with respect to the direction of the applied magnetic field to orient the distal end of the sheath (Col. 11 II. 31-38).

However, Howard does not disclose the tip of the catheter being formed of metallic material that is attracted to a magnet and being oriented by the magnetic field.

Tillander discloses a catheter tip formed of a metallic material that is attracted to a magnet and being oriented by the magnetic field (Col. 3 II. 3-19).

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It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the distal tip of Howard with that of Tillander in order to bend the tip into a selected artery as taught by Tillander (Col. 3 II. 14-15).

3. Claims 6, 13, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson 5,845,646 in view of Tillander.

Lemelson discloses a system comprising: a catheter having a catheter body having a proximal end and a distal end terminating in distal tip, wherein the catheter body and the is capable of being mechanically pushed to advance the distal tip; an energy source coupled to said distal tip (Col. 14 II. 12-25); a magnetically active element located proximate said distal tip of said catheter body; and a magnet outside the body that applies a magnetic field to orient the distal tip of the catheter such that the catheter advances in a direction determined by the magnetic orientation of the distal end of the sheath (Col. 13 I. 60- Col. 14 I. 11).

However, Lemelson does not disclose a sheath, having a sheath body, said sheath body having a proximal end and having a distal end; a lumen extending through said sheath body from said proximal end to said distal end.

The Examiner takes official notice that it is notoriously old and well known in the art to provide a sheath having a proximal and distal ends over a catheter.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Lemelson by providing a sheath over the catheter of Lemelson in order to facilitate easier mobility of the catheter through the vasculature. Lemelson further does not disclose the tip of the catheter being formed of metallic material that is attracted to a magnet and being oriented by the magnetic field.

Tillander discloses a catheter tip formed of a metallic material that is attracted to a magnet and being oriented by the magnetic field (Col. 3 II. 3-19).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the distal tip of Howard with that of Tillander in order to bend the tip into a selected artery as taught by Tillander (Col. 3 II. 14-15).

Regarding claims 13 and 17-19: Lemelson further discloses utilizing ultrasonic imaging (Col. 1 II. 7-29), laser imaging (Col. 14 II. 18-20), and a fluid directing element (Col. 14 II. 20-25).

**4.** Claims 8-12, 14-16, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Tillander in view of substitution of known equivalents.

Lemelson discloses the invention essentially as claimed as discussed in claim 6 above. Lemelson further discloses using eddy currents of the magnetic field to heat a magnetic element (Col. 14 II. 33-38).

However, Lemelson does not disclose using radio frequency, laser energy applied to a thermally conductive element, or resistance heating elements for heating.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Lemelson by substituting the magnetically driven heating for optical laser energy or resistance heating elements and electrical energy since it has been held that the selection of a known component is obvious when it does not produce a new or unexpected result; *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

## Response to Arguments

5. Applicant's arguments with respect to claims 6-19, 29 and 30 have been considered but are moot in view of the new ground(s) of rejection.

## Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30AM-3PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

/(Jackie) Tan-Uyen T. Ho/ Supervisory Patent Examiner, Art Unit 3773